U.S. Nuclear Regulatory Commission
Office of Nuclear Reactor Regulation

NRR OFFICE INSTRUCTION

Change Notice

Office Instruction No.:	**LIC-111**	
Office Instruction Title:	**Regulatory Audits**	
Effective Date:	**December 29, 2008**	
Approved By:	**James T. Wiggins**	
Date Approved:	**December 16, 2008**	
Primary Contacts:	**Diane T. Jackson** **NRR/DSS** **Diane.Jackson@nrc.gov** **301-415-8548**	**David J. Wrona** **NRR/DLR** **David.Wrona@nrc.gov** **301-415-2292**
Responsible Organizations:	**NRR/DSS**	**NRR/DLR**

Summary of Changes: This is the initial issuance of this Office Instruction. The objective of this instruction is to provide guidance to staff who conduct regulatory audits.

Training: None

ADAMS Accession No.: ML082900195

U.S. Nuclear Regulatory Commission
Office of Nuclear Reactor Regulation

NRR OFFICE INSTRUCTION

Change Notice

Office Instruction No.: **LIC-111**

Office Instruction Title: **Regulatory Audits**

Effective Date: **December 29, 2008**

Approved By: **James T. Wiggins**

Date Approved: **December 16, 2008**

Primary Contacts:

Diane T. Jackson
NRR/DSS
Diane.Jackson@nrc.gov
301-415-8548

David J. Wrona
NRR/DLR
David.Wrona@nrc.gov
301-415-2292

Responsible Organizations: **NRR/DSS** **NRR/DLR**

Summary of Changes: This is the initial issuance of this Office Instruction. The objective of this instruction is to provide guidance to staff who conduct regulatory audits.

Training: None

ADAMS Accession No.: ML082900195

OFFICE	RE:NRR/DSS/SRXB	PM:NRR/DLR/RPOB	NRR/DLR	NRR/DSS	NRR/DPR
NAME	DJackson	DWrona	BHolian/ Sam Lee for	WRuland	MCase/ TBlount for
DATE	10/09/2008	10/09/2008	11/12/2008	10/29/2008	11/07/2008
OFFICE	NRR/DCI	NRR/DE	NRR/DRA	NRR/DORL	NRR/DIRS
NAME	MEvans	PHiland	MCunningham	JGitter	FBrown
DATE	10/20/2008	10/24/2008	10/30/2008	10/15/2008	10/22/2008
OFFICE	OGC	PMDA	NRR		
NAME	Mary Baty	Mary Givvines	JWiggins		
DATE	11/12/2008	11/26/2008	12/16/08		

OFFICIAL RECORD COPY

NRR OFFICE INSTRUCTION
LIC-111

Regulatory Audits

1. POLICY

It is the policy of the Office of Nuclear Reactor Regulation (NRR) to provide guidance for its staff to meet the requirements and performance goals established in legislation, regulations, the Agency's strategic plan, and office-level operating plans. Completion of regulatory audits supports the NRC's Effectiveness & Efficiency Goals.

2. OBJECTIVES

This office instruction provides guidance to staff who conduct regulatory audits of information, developed and maintained by licensees, applicants, vendors, and other entities related to nuclear reactor regulation (herein, referred to as licensees).

3. BACKGROUND

3.1 Definitions

Regulatory Audit

A regulatory audit is a planned, license or regulation-related activity that includes the examination and evaluation of primarily non-docketed information. A regulatory audit is conducted with the intent to gain understanding, to verify information, and/or to identify information that will require docketing to support the basis of the licensing or regulatory decision.

Audit Team Member

A staff member or contractor with the knowledge and skills necessary to effectively perform the regulatory audit activities who is assigned by the responsible supervisor.

Audit Leader

The staff member with the overall responsibility for the conduct of the regulatory audit who is assigned by the responsible supervisor.

3.2 General

The Code of Federal Regulations requires licensees to provide written correspondence to the NRC. Additional requirements are provided for the licensee's maintenance and retention of documents. For example, Title 10 of the Code of Federal Regulations sections 2.101 (10 CFR 2.101), 50.4 (10 CFR 50.4), and 54.17 (10 CFR 54.17) require applications for permits and licenses, and amendments to applications, and applications for amendment of permits and licenses to be sent to the NRC. 10 CFR 50.71, "Maintenance of Records, Making of Reports," requires that records connected to licensed

activities be maintained by the licensee. 10 CFR 54.37, "Additional Records and Record Keeping Requirements," requires that license renewal applicants maintain documents demonstrating compliance with the requirements of 10 CFR Part 54 in auditable and retrievable form.

In most circumstances, a regulatory audit is part of a larger regulatory action. Performing a regulatory audit may allow the staff to more efficiently conduct its review or gain insights on the licensee's programs or processes. For example, when a licensing action request is reviewed by the NRC, the information that the staff relies upon to make the safety determination must be submitted. However, there may be supporting information retained as records under 10 CFR 50.71 and/or 10 CFR 54.37 that, although not required to be submitted as part of the licensing action, would help the staff better understand licensee submitted information.

A regulatory audit may focus on specific documents or may be performed by sampling analyses and information in support of the regulatory action. A regulatory audit may be conducted at one facility, all affected facilities or a sampling, as necessary to support the regulatory action.

A regulatory audit may affect more than one NRC office. The audit leader should consider if coordination with other offices is appropriate to support technical consistency.

The areas the staff may conduct a regulatory audit include, but are not limited to the following:

- license renewal applications,
- plant-specific licensing action requests or topical reports,
- generic communications,
- development of temporary instructions and inspection procedures, and
- periodic reviews of licensee commitment management programs (i.e., PM Audits).

Regulatory audits allow the staff to do the following:

- Gain a better understanding of the detailed calculations, analyses and/or bases underlying the formal application and confirm the staff's understanding of the application.

- Identify additional information that is necessary for the licensee to supplement its application for the staff to reach a licensing or regulatory decision.

- Establish an understanding of an area where the staff has identified potential concerns to allow the staff to issue clear requests for information and for the licensee to provide quality and timely responses.

- Establish an understanding of potential concerns to inform future regulatory actions or decisions, such as generic communications.

- Establish an understanding of proposed modification(s) or resolution(s) in support of a regulatory action or decision.

- Confirm the licensee's implementation of programs or processes that track commitments or industry initiatives.

The types of information that the staff may audit include, but not limited to, the following: (1) process information, (2) procedures, (3) calculations, (4) design information, and (5) computer code information.

3.3 Selection of Audit Leader and Members

The audit leader and audit members are designated by the responsible supervisor. Audit members may include project managers, technical reviewers, senior level staff, supervisors, and contractors.

Audit members should possess the technical and/or regulatory knowledge to work effectively and efficiently in the audit setting and interact with the licensee's staff, and have completed allegation training. Additionally, the audit leader should possess the ability to coordinate small groups and interact with the licensee's staff and management. These skills are assessed by the supervisor when assigning members to perform audit activities.

It is the expectation that at least one audit member will be qualified through NRR Office Instruction (OI) ADM-504, "Qualification Program" or Inspection Manual Chapter (IMC) 1245, "Inspector Qualification." However, the selection is at the discretion of the supervisor.

4. PLANNING, CONDUCTING, AND DOCUMENTING REGULATORY AUDITS

The amount of detail included in the audit preparation, audit plan, execution of the audit, and audit documentation should be commensurate with the scope, complexity, and size of the audit. That is, a large team on-site audit should provide more details in the audit plan, as well as, ensure more coordination with the Region, project manager, and licensee, than a one-person audit of selected calculations.

4.1 Regulatory Audit Preparations

Regulatory audits may be conducted at any facility, including a plant site, licensee's headquarters, contractor or vendor site, and in NRC buildings. Regulatory audits conducted at reactor sites should be coordinated with the licensee, regional NRC office, and resident inspectors. The focal point for this coordination should normally be the NRR PM for the nuclear power plant or non-power reactor. In the case of a license renewal regulatory audit, the NRC license renewal PM may coordinate with the licensee, regional office, and inform the NRR PM for the nuclear power plant or non-power reactor.

Once approved by the audit leader's supervisor, the audit plan should be shared with the audit team members and the licensee so they can prepare for the regulatory audit. The audit leader should consider holding a pre-audit meeting

with the audit team members and responsible supervisor to discuss assignments and expectations. The audit leader or cognizant PM should discuss the plan with the licensee and request the licensee provide space, documentation, access to personnel, and other necessary items. To the extent possible, the audit leader should prepare a list of documents that are needed and communicate the list to the licensee either orally or in writing, typically 14 days before the regulatory audit.

4.2 Regulatory Audit Plans

A regulatory audit plan should provide a clear, succinct overview of the regulatory audit activities. The audit plan provides structure and organization for the regulatory audit and serves as an integral planning tool for the audit member(s).

The level of detail of the regulatory audit plan should be commensurate with the desired audit scope. The audit plan is normally 1-2 pages in length, and should follow the recommended contents, as applicable, listed below:

a. Background. This section provides a brief introduction of the licensee and application associated with or reason for the regulatory audit.

b. Regulatory Audit Bases. This section identifies the documents upon which the regulatory audit is based. This may include, but not limited to, sections of the licensing action request, 10 CFR 54, applicable sections of the standard review plan (SRP), and/or regulatory guides.

c. Regulatory Audit Scope or Methodology. This section identifies the areas of focus for the regulatory audit (e.g., process information, calculations) or describes the method in which the regulatory audit will be conducted.

d. Information and Other Material Necessary for the Regulatory Audit. This section identifies known information or material needed by the audit member(s) to complete the regulatory audit. This could include, but is not be limited to, licensee reports, calculations, and computer codes.

e. Team Assignments. This section identifies the audit members and their respective area(s) of responsibility.

f. Logistics. This section documents the date and location(s) for the regulatory audit; entrance and exit briefing dates and times; and audit schedule.

g. Special Requests. This section may document any requests of the licensee by the team to support the audit.

h. Deliverables. This section identifies the deliverables for the regulatory audit and establishes the schedule for the deliverables. At a minimum, a schedule for issuance of the regulatory audit summary should be provided.

i. References. This section identifies references that may be applicable to the regulatory audit.

4.3 Conducting Entrance, Closing, Exit, and Status Briefings:

For audits that require more than one day, an entrance briefing with the licensee is recommended. Entrance briefings should be scheduled in advance and should be conducted as soon as practicable after arrival. At the entrance briefing, the audit leader should review key elements of the regulatory audit plan with the licensee.

For multiple-day audits, the audit leader should consider status briefings with the responsible NRC supervisor. As needed, the audit leader should also consider periodic status briefings with the licensee to discuss progress and potential issues identified. The audit leader should consider briefing the responsible supervisor on the preliminary audit results prior to the closing or exit briefing.

If a regulatory audit is conducted in several phases, at multiple locations and/or discontinuous time frames, the audit team member(s) should conduct a closing briefing at the end of each phase. The closing briefing should summarize the status of the audit at the time of the closing and detail the logistics of the subsequent audit phase.

An exit briefing should be conducted at the conclusion of the regulatory audit. Preliminary results should be presented emphasizing that these are preliminary in nature and subject to NRR management review. It should be noted to the licensee that the agency will communicate any significant changes between the preliminary audit results and the regulatory audit summary prior to issuance.

Note: Similar to inspections, entrance and exit briefings are generally neither noticed nor conducted as public meetings.

4.4 Conducting Regulatory Audit Activities

Audit member(s) activities during the regulatory audit and interactions with the licensee should be clearly linked to the staff's guidance, such as in the SRP, recognizing that much of the material discussed and audited may not require docketing. Information that is needed to support the staff's licensing or regulatory decision should be placed on the docket and in ADAMS. This may be accomplished through a request for additional information (RAI), formal correspondence from the licensee or staff action.

Audit member(s) should use their time to audit detailed reports, design record files, and process information or procedures not required to be submitted by the licensee. Discussions with the licensee's staff may be held for the audit member(s) to gain a better understanding of how the information being audited was used by the licensee.

Audit members may review controlled copies of the licensee's records and documents at any time during the regulatory audit. When the licensee uses a form to request controlled documents from its storage facility or document control clerks, the audit members may fill out this form following the licensee's procedures. This documentation cannot be removed from the licensee's property or disposed of without the owner's permission.

In general, non-docketed licensee information should not be removed from the audit site. The audit summary should include sufficient information to retrieve audited documents through the licensee's document control system. If certain information is identified to be docketed, the licensee should be requested to submit the information. If necessary, audit members may remove licensee documents from the audit site to assist in writing the audit summary. However, this practice should be kept to a minimum. Licensee documents removed from the audit site must be handled given the appropriate considerations such as those discussed in Section 4.6.

Prior to removing any of the licensee's documents that will be maintained, possessed, and controlled by the NRC, the licensee will have the opportunity to provide and mark the documents in accordance with 10 CFR 2.390(b).

During a regulatory audit, the staff may identify a potential inadequacy, programmatic deficiency, non-compliance or operability concern. An issue that may be an immediate safety or operability concern should be reported to NRC management at once. Potential issues should be communicated to NRR and regional management, the licensee, and/or resident inspectors, as appropriate. If follow-up or an inspection is necessary, the staff may plan an inspection in accordance with NRC procedures.

4.5 Documenting the Regulatory Audit

At the completion of the regulatory audit, a regulatory audit summary should be developed in a timely manner. Depending on scope of the audit, the regulatory audit summary may be documented as:

- a letter to the licensee,
- a detailed summary report, or
- an internal memorandum to the responsible supervisor or cognizant project management branch.

The regulatory audit summary should be placed on the docket and in ADAMS within 90 days of the completion of the audit or before the regulatory action that the audit supports is completed, which is shorter. The regulatory audit summary may be publically available, as appropriate given considerations such as those discussed in Section 4.6. If multiple audits are conducted (e.g., license renewal audits), the same type of document should be used to convey the audit results.

The regulatory audit summary should provide a clear, succinct summary of the audit activities, and as applicable should:

- identify the audit location and dates,
- list the audit team members,
- list licensee staff that participated in substantive discussions,
- list documents that were audited,
- describe the audit activities,
- describe the closing or exit briefing,
- identify RAI(s) or potential RAI(s) that were discussed or that will be issued based on the audit,

- describe open item(s) and the proposed closure path(s), and
- describe deviations from the audit plan.

The list of the audited documents should be sufficiently detailed to retrieve the information through the licensee's document control process. This may include title, date, revision number, and supplement number.

If audit open items are necessary, a closure path should be provided. An exception would be in the case of planned multi-phase audits. If RAIs are necessary, they should be provided to the project manager with the technical supervisor's concurrence and in accordance with the audit plan schedule.

The staff should not make final licensing conclusions or staff findings in the audit summary since licensing and regulatory decisions cannot be made solely based on an audit. However, audit conclusions may be drawn. The staff may refer to the regulatory audit summary or include a discussion of the audit activities in a safety evaluation.

The audit leader is responsible for ensuring that the content of the regulatory audit summary is consistent with the audit activities and the content of the exit briefing. If the summary differs significantly from the exit briefing, the audit leader and responsible NRR management should discuss those differences with the licensee before issuing the regulatory audit summary.

4.6 Controlling and Disposing of Documents and Records

Audit members have the responsibility to follow Agency and Office policies on handling documents, including guidance on:

- Retaining official agency records (OARs)
- Responding to Freedom of Information Act (FOIA) requests
- Handling sensitive unclassified non-safeguards information (SUNSI) (including proprietary information)
- Handling safeguards information
- Handling draft licensee information
- Handling working files and supporting material
- Handling pre-decisional information
- Dispositioning Records

Official Agency Records

Audit members have the responsibility to preserve OARs. Do not make documents or portions of documents that fall within the exempt categories, such as 10 CFR 2.390 and 10 CFR 9.13, publicly available. For more information see Management Directive (MD) 3.53, "NRC Records and Document Management Program" and the Office of Information Systems (OIS) website - http://www.internal.nrc.gov/ois/divisions/irsd/records-mgt/index.html - which has an interactive tool to assist in deciding whether a document is an official record or some other type of documentary material.

Provided below is excerpted guidance from OIS on determining OARs:

- Was it created or received by my organization to conduct agency business?

- Does it contain information that documents agency functions, policies, decisions, operations, procedures, mission or activities?
- Is it something on which you took action, or commented on, on behalf of the agency?
- Does it document business decisions, actions, advice, order of events, when something happened or who was involved in it?
- Is it an original document that doesn't exist elsewhere but is work-related?

If a hearing has been requested or if there is a potential for a hearing request, there are further requirements on documents removed from the licensee's site. NRR Office Instruction LIC-201, "NRR Support to the Hearing Process," provides detailed guidance on the staff's responsibility to retain documents related to its reviews and audits if a hearing has been or potentially will be requested.

Freedom of Information Act Requests

Audit members have the responsibility to adhere to the guidelines for a FOIA request. Any document, docketed or not, in an NRC's employees possession at the time of a FOIA request must be considered under the FOIA criteria. For more information see MD 3.1, "Freedom of Information Act," and NRR Office Instruction ADM-307, "Freedom of Information Act Requests."

Proprietary, Sensitive, and Safeguards Information

Audit members have the responsibility to protect the licensee's sensitive unclassified non-safeguards information (SUNSI), including proprietary information, and safeguards information. If information is removed from the audit site, all precautions should be followed to prevent the inadvertent release of SUNSI and safeguards information. See MD 12.2, "NRC Classified Information Security Program," MD 12.6, "NRC Sensitive Unclassified Information Security Program," and MD 12.7, "NRC Safeguards Information Security Program" for more details.

Draft Licensee Information

In general, draft information should not be invited or physically accepted by audit members. If draft information needs to be reviewed as part of the audit, it should be preserved as an OAR when it is needed to provide a complete record of the decision making process. Draft documents that are subsequently replaced by formal submittals need to be placed in ADAMS if they meet the criteria of Management Directive 3.53. That is, if the draft licensee information was received by the agency in connection with the transaction of agency business, the draft information should be preserved if it is necessary for a proper understanding of the agency's formulation and execution of basic policies, decisions, actions or responsibilities.

For more information see NRR Office Instruction COM-203, "Informal Interfacing and Exchange of Information with Licensees and Applicants" and NRR Office Instruction LIC-101, "License Amendment Review Procedures."

If a hearing has been or may be requested, all communications between the staff and the licensee should be retained. NRR OI LIC-201 provides guidance on the staff's responsibility to retain NRC staff-licensee communications.

Working Files and Supporting Materials

True supporting materials are documents that are necessary to substantiate the final document or decision trail. Supporting materials are not working files. Supporting materials are part of the official record.

Working files consist of documents such as personal notes, rough notes, calculations, or drafts assembled or created and used to prepare or analyze other documents. They can contain background files, such as worksheets, questionnaires, extra copies of articles, reports, studies, information, and documentary materials that do not meet the requirements to be records and, thus, are not part of the agency's official record collections. However, working files are not exempt from FOIA consideration.

Working files should be maintained and filed with the official record for the purposes of adequate and proper documentation if they meet both of the following conditions: 1) They were circulated or made available to employees, other than the creator, for official purposes such as approval, comment, action, recommendation, follow up, or to communicate with agency staff about agency business, and 2) They contain unique information such as substantive annotations or comments included therein, that adds to the proper understanding of the agency's formulation and execution of basic policies, decisions, actions, or responsibilities.

Unless otherwise specified, working files, such as personal notes, informal comments, and drafts, can be destroyed/deleted once they are incorporated into a final product. Special attention should be given to notebooks, calculations, and other background material that may contain information needed to supplement formal records (i.e., supporting material). Comments received during a formal review by outside experts and the public should be carefully documented for the record, either by keeping the original comments themselves, or if volume is extensive, keeping a summary of the comments, and how they were used.

Pre-Decisional NRC Information

Consistent with NRC policies, procedures, and regulatory requirements, do not show or physically provide to the licensee, or anyone external to the NRC, any portion of the audit summary before it is formally issued or the final licensing or regulatory decision has been made. Only the explicit written permission of the NRC Executive Director for Operations (EDO) can override this policy.

If an audit member inadvertently or improperly releases pre-decisional information, the staff shall immediately inform the EDO in writing of the release and the facts about the release. The responsible office shall take corrective action to retrieve the documentation and prevent recurrence of such a release. See MD 3.4, “Release of Information to the Public,” for a more detailed explanation.

Records Disposition

Information necessary to support the licensing or regulatory decision should be placed on the docket by the licensee or NRC staff. Licensee documents in the possession and control of the staff and not otherwise formally submitted by the

licensee should be retained and placed on the docket and in ADAMS if the criteria in MD 3.53 are satisfied. The staff should properly dispose of licensee and draft NRC documents as appropriate for the classification of the information. A list of the audited documents will be included in the regulatory audit summary, which becomes an official agency record.

Materials created by an audit member for the audit member's own use in performing his or her job, and which are not shared (and are not otherwise required by NRC policy to be maintained), may be discarded at the audit member's discretion.

5. RESPONSIBILITIES AND AUTHORITIES

Director, NRR

Establish the policies contained within this office instruction related to the conduct of regulatory audits performed by the staff.

Division Directors (ALL)

Responsible for the oversight of all regulatory audits conducted within the auspices of their program/process.

Branch Chiefs (ALL)

Responsible for the planning and implementation of regulatory audits conducted within the auspices of their programs and processes.

Responsible Branch Chief (of audit leader)

Assigns individual as the audit leader. Assigns or coordinates responsible individuals as audit team members. Approves audit plan. Ensures timely deliverables as established in the audit plan.

All NRR Staff Members

All NRR staff members are responsible for following the procedures in this office instruction. Staff members assigned to perform regulatory audit activities will follow the guidelines described in this office instruction and references.

6. PERFORMANCE MEASURES

None. Regulatory audits are generally performed as part of a larger program or as needed to support a regulatory and licensing decision.

Branch chiefs should ensure timeliness of deliverables established in the audit plan.

7. PRIMARY CONTACTS

Diane T. Jackson
NRR/DSS
301-415-8548

David J. Wrona
NRR/DLR
301-415-2292

8. RESPONSIBLE ORGANIZATIONS

NRR/DSS and NRR/DLR

9. EFFECTIVE DATE

December 29, 2008

10. REFERENCES

A. Title 10 of the Code of Federal Regulations Part 2, “Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders.”

B. Title 10 of the Code of Federal Regulations Part 9, “Public Records.”

C. NRC Management Directive 3.1, “Freedom of Information Act.”

D. NRC Management Directive 3.4, “Release of Information to the Public.”

E. NRC Management Directive 3.23, “Mail Management.”

F. NRC Management Directive 3.53, “NRC Records and Document Management Program.”

G. NRC Management Directive 12.2, “NRC Classified Information Security Program.”

H. NRC Management Directive 12.6, “NRC Sensitive Unclassified Information Security Program.”

I. NRC Management Directive 12.7, “NRC Safeguards Information Security Program.”

J. NUREG-0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants.”

K. NRR Office Instruction ADM-504, “Qualification Program.”

L. NRR Office Instruction ADM-307, “Freedom of Information Act Requests.”

M. NRR Office Instruction COM-203, “Informal Interfacing and Exchange of Information with Licensees and Applicants.”

N. NRR Office Instruction LIC-101, “License Amendment Review Procedures.”

O. NRR Office Instruction LIC-105, “Managing Regulatory Commitments Made by Licensees to the NRC.”

P. NRR Office Instruction LIC-201, “NRR Support to the Hearing Process.”

Q. Inspection Manual Chapter 0301, “Coordination of NRC Visits to Commercial Reactor Sites.”

R. Inspection Manual Chapter 0620, “Inspection Documents and Records.”

S. Inspection Manual Chapter 1245, “[Inspector] Qualification Program for the Office of Nuclear Reactor Regulation Programs”

Enclosures:
Appendix A - Change History

Appendix A - Change History

Office Instruction LIC-111

Regulatory Audits

LIC-111 Change History - Page 1 of 1			
Date	**Description of Changes**	**Method Used to Announce & Distribute**	**Training**
12/16/08	Initial Issuance	E-mail to NRR staff	Offer presentation to all branches and divisions

ENCLOSURE